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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,741	08/04/2000	Brent Belding	ACS-53498(21061)	2770

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No. 09/632,741	Applicant(s) BELDING ET AL.
Examiner Urmi Chattopadhyay	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 30 August 2002.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-64 is/are pending in the application.  
4a) Of the above claim(s) 6,7,10,12,27,29,39 and 45-64 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1,2,4,5,8,9,11,13-19,21,22,25,26,28,30-35 and 38,40-44 is/are rejected.
- 7)  Claim(s) 3,20,23,24,36 and 37 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 04 August 2000 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other:

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**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 8/30/02 has been entered as Paper No. 6. Changes to the claims have been approved by the Examiner.

***Election/Restrictions***

2. Examiner would like applicant to note that previously examined claim 7 has now been withdrawn from consideration for being dependent on a withdrawn claim, claim 6. The claims being considered on the merits are 1-5, 8, 9, 11, 13-26, 28, 30-38 and 40-44.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 8, 9, 13, 16-19, 21, 22, 25, 26, 30, 31, 33-35, 40, 41, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Solar (USPN 5,549,635).

Solar discloses a catheter assembly for delivering an endoprosthesis with all the elements of claims 1, 18 and 35. See Figured 4a-4c for a catheter (30) having proximal and distal end (34) portions, an expandable member (38) associated with the distal end portion, an endoprosthesis (10) disposed on the expandable member, and a sheath (40) disposed on the catheter and over the

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endoprosthesis, wherein the sheath is configured to rupture during expansion of the expandable member (column 6, lines 50-62).

Claims 2, 19 and 35, see column 6, lines 59-62 for weakened section configured to rupture during expansion of the expandable member.

Claims 4, 5, 21, 22 and 35, see column 7, lines 3-9 for sheath being stretched over and column 6, lines 54-59 for sheath being secured to the expandable member and secured to the distal end portion of the catheter by way of the expandable member.

Claims 8 and 25, see Figure 4c for expandable member including an inflatable dilatation balloon (38).

Claims 9, 26 and 35, see Figure 4a for endoprosthesis being a stent (10).

Claims 13, 30 and 40, see column 7, lines 1-4 for sheath being of elastomeric material.

Claims 16, 17, 31, 33, 34, 41, 43 and 44, see column 7, line 2 for sheath being formed from polyurethane.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11, 28 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solar.

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Solar discloses a catheter assembly for delivering an endoprosthesis with all the elements of claims 1, 18 and 35. Solar does not disclose expressly that the catheter includes an over-the-wire intravascular catheter, as required by claims 11, 28 and 38. However, it appears from Figures 5a-5c that the catheter could include an over-the-wire intravascular catheter. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the catheter include an over-the-wire intravascular catheter because Applicant has not disclosed that an over-the-wire intravascular catheter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with other catheters because the ability for the sheath to rupture during expansion of the expandable member is not affected by the type of catheter used. Therefore, it would have been an obvious matter of design choice to modify Solar to obtain the invention as specified in claims 11, 28 and 38.

7. Claims 14, 15, 32 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solar in view of Makower et al. (USPN 6,302,875 B1).

Solar discloses a catheter assembly with all the elements of claims 1, 18 and 35, but is silent to the additional limitation of the sheath being formed from polyurethane with a shore hardness of 45D or lower or a biodegradable material, as required by claims 14 and 15, 32, 42, respectively. Makower et al. teaches a catheter with a sheath formed from polyurethane having a shore hardness of less than 45D or a biodegradable material, elastin, in order to impart a less rigid and less hard region in the sheath. It would have been obvious to one of ordinary skill in

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the art at the time of applicant's invention to look to the teachings of Makower et al. to make the sheath of Solar of a polyurethane having a shore hardness of less than 45D or a biodegradable material in order to impart less rigid and hard characteristics to the sheath so that it will expand with less pressure. See column 7, lines 9-28.

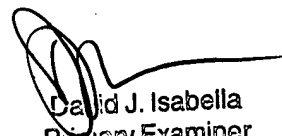
*Allowable Subject Matter*

8. Claims 3, 20, 23, 24, 36 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

  
Urmi Chattopadhyay  
Art Unit 3738

  
David J. Isabella  
Primary Examiner